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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/746,375	12/22/2000	Scott R. Presnell	99-106	2186

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EXAMINER
O HARA, EILEEN B

ART UNIT	PAPER NUMBER
1646	5

DATE MAILED: 03/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/746,375	PRESNELL ET AL.	
	Examiner	Art Unit	
	Eileen B. O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11 and 14, drawn to polynucleotides encoding ZCYTO18 protein, vectors, host cells and a method for producing a polypeptide recombinantly, classified in class 536, subclass 23.5, class 435, subclasses 320.1, 252.3 and 69.1, for example.

II. Claims 12 and 13, drawn to ZCYTO18 polypeptides, classified in class 530, subclass 350.

III. Claims 15-18, drawn to antibodies to ZCYTO18 and method of making antibodies, classified in class 530, subclass 388.22, for example.

IV. Claims 19 and 20, drawn to a method of screening for antagonists or agonists of ZCYTO18, classified in class 435, subclass 7.1.

V. Claims 21, 23 and 28, drawn to methods of screening for a genetic abnormality, cancer or inflammation by nucleic acid hybridization, classified in class 435, subclass 6.

VI. Claims 22 and 27, drawn to methods of detecting cancer or inflammation by antibody-protein binding, classified in class 436, subclass 501, for example.

VII. Claims 24-26, drawn to a method of treatment by administration of ZCYTO18 polypeptide, classified in class 514, subclass 2.

2. The inventions are distinct, each from the other because of the following reasons:

The polynucleotides of invention I is related to the polypeptides of invention II by virtue of encoding the same. The polynucleotides have utility for the recombinant production of the protein in a host cell. Although the polynucleotides and proteins are related since the polynucleotides encode the specifically claimed proteins, they are distinct inventions because the protein products can be made by another materially different process, such as by synthesis or purification from the natural source. Further, the polynucleotides may be used for processes other than the production of the proteins, such as nucleic acid hybridization assays.

The proteins of invention II are related to the antibodies of invention III by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural receptor of the protein.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of invention I are used in the method of screening for a genetic abnormality, cancer or inflammation by nucleic acid hybridization, but

the nucleic acids can also be used in a method of recombinantly producing the protein, which is a materially different method.

Invention I and each of inventions III, IV and VII are related as a process of making and a process of using a common product. The polynucleotides of invention I encode the polypeptides, which are used in the methods of treatment with the polypeptides of invention VII, and which polypeptides are the cognate antigens necessary for production of the antibody of invention III which is used in the method of screening for agonists or antagonists of the polypeptides, but the nucleotides may also be used as probes in a method of hybridization, which are materially different methods. The processes are patentably distinct because of different starting and ending points, method steps and goals.

Inventions II and each of inventions IV and VII are related as product and process of use. In the instant case the polypeptides of invention II can be used in the method of screening for antagonists or agonists of the polypeptides of invention IV or in the method of treatment of invention VII, which are materially different methods.

Inventions II and VI are related in that the polypeptide is quantitated by the antibody in the method of diagnosis that is invention VI, but the polypeptide is not used in the method.

Inventions III and each of inventions IV and VI are related as product and process of use. In the instant case the antibodies of invention III can be used in the method of screening for agonists or antagonists of the polypeptide of invention IV or in the method of detecting cancer or inflammation by antibody-protein binding, which are materially different methods having different starting materials, steps and goals.

Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotides are not used or defined in the method of detecting cancer or inflammation by antibody-protein binding.

Inventions II and V are also unrelated. In the instant case the polypeptides are not used or defined in the methods of nucleic acid hybridization.

Invention III is also unrelated to each of inventions V and VII. The antibodies are not used or defined in the methods of nucleic acid hybridization or treatment by administration of polypeptide.

Inventions IV-VII are unrelated to each other. The different methods require different starting materials, and have different method steps and goals.

Further Restriction Within Group I

3. Applicants' claims are drawn to numerous patentably distinct nucleic acid sequences encoding fusion protein. If group I is elected, further restriction *within* the group is required, as follows:

The claims are drawn to numerous patentably distinct nucleic acids, each of which constitutes a patentably distinct product. Applicant is required to elect a single invention of a nucleic acid encoding a fusion protein, selected from the group consisting of:(i.e. elect one from the following Markush group):a nucleic acid comprising a polynucleotide encoding a fusion

protein selected from the group consisting of the following regions of SEQ ID NO: 3: residues 1-21, 41-53, 80-91, 103-116, 149-162 or 23-167.

Further Restriction Within Group III

4. Applicants' claims are drawn to numerous patentably distinct antibodies to regions of polypeptide sequences. If group III is elected, further restriction *within* the group is required, as follows:

The claims are drawn to numerous patentably distinct antibodies to specific polypeptide sequences, each of which constitutes a patentably distinct product. Applicant is required to elect a single invention of an antibody to a single polypeptide, selected from the group consisting of: (i.e. elect one from the following Markush group): an antibody to a polypeptide having an amino acid sequence selected from the group consisting of the following regions of SEQ ID NO: 3: residues 29-34, 121-126, 134-139, 137-142, 145-150, 41-53, 80-91, 103-116 or 149-162.

Applicant is advised that this is not a species election.

Although the classifications for these various nucleic acids are overlapping, for instance 536/23.1 or 530/388.22, each represents a patentably distinct product with distinct physical and functional characteristics. Further, the search for more than one product would be burdensome, because, in the case of the nucleic acid sequences, many are claimed not by nucleic acid sequence, but by the sequence of the protein encoded thereby, and requires a search of the corresponding region of SEQ ID NO: 1 as well as a 'reverse translation' search of the corresponding region of SEQ ID NO: 3, such that each individual sequence requires two

sequence searches which are not required for any of the other sequences, or alternatively by virtue of comprising only a small portion of a disclosed nucleic acid or polypeptide, which requires a separate "word search" of the nucleic acid and protein databases. It cannot even be said that the search for nucleic acids encoding amino acids 1-167 of SEQ ID NO: 3 would reveal art pertaining to, for instance a region consisting of amino acids 29-34 of SEQ ID NO: 3, as the latter could be found embedded in a completely different protein, and therefore each of these small fragments (6-21 amino acids in length) would have to be searched separately, which would be a burden. Accordingly, restriction is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification, recognized divergent subject matter, and the need for non-coextensive literature search and/or separate sequence database searches, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

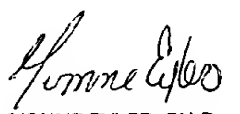
Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner



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